4. Requirements for consent

4.1. Why is it necessary to obtain patient consent and warn patients about material risks?

Adults with capacity have a right to decide what happens to their own bodies. This means that they have the right to consent to treatment, refuse to consent to treatment for any reason, or withdraw their consent, even if refusal or withdrawal of treatment is likely to lead to serious injury or death. These principles are reflected in the law that governs consent to medical treatment. As a general rule, no operation, procedure or treatment may be undertaken without prior consent from the patient or, if the patient lacks capacity, from the patient's substituted decision maker.

The only exceptions are:

- in an emergency when the patient lacks capacity and the patient's express wishes are unknown; or
- where the law otherwise allows or requires treatment to be given without consent.

Consent to the general nature of a proposed operation, procedure, or treatment must be obtained from the patient or, if the patient lacks capacity, from the patient's substituted decision maker. Failure to do this could result in legal action for assault and battery against the Health Practitioner who provided the care, irrespective of whether the patient suffered harm as a result of the procedure.

Health Practitioners also have a legal obligation to provide patients (or substituted decision makers) with information, including warnings, about any material risks involved in the proposed procedure or treatment. Failure to do so may also give rise to legal action for negligence. For further information on material risks see section 4.8.

Obtaining consent and adequately informing patients about their treatment options and the risks and benefits arising are an established part of good clinical practice.

Further guidance

- Section 4.8 – How do I properly inform a patient about a procedure and warn of material risks?
- NSW Health Policy Directive *Your Health Rights and Responsibilities* (PD2011_022)

4.2. When can treatment be provided without consent?

4.2.1. Emergency treatment

Consent is generally not required where the patient lacks capacity and immediate treatment is necessary to save a person's life or prevent serious injury to their health. Treatment in this context extends to all actions reasonably required to provide the treatment, such as restraint. Treatment (other than Special Medical Treatment) can also be provided without consent to alleviate significant pain and distress. However, treatment cannot be provided without consent in an emergency if providing the treatment would be contrary to a valid prior refusal of treatment, such as an ACD.

This emergency principle also applies to Minors. Pursuant to section 174 of the *Children and Young Persons (Care and Protection) Act 1998*, consent is not required to treat a child or young person, regardless of capacity, if the treatment is required urgently to save the life or prevent serious damage to the health of the child or young person.

Where treatment is provided without consent in an emergency, this must be documented in the patient's Health Record.

Further guidance

- Section 6.2 – Refusal of treatment using an Advance Care Directive
- Section 8 – Minors

4.2.2. Treatment lawfully authorised or required

Consent of the patient (or their Person Responsible) is not required for treatment which is authorised by legislation or by an order of a court, Tribunal or authorised person.

Orders

Treatment orders can be made by courts or Tribunals. Examples include an order of the NSW Civil and Administrative Tribunal (**NCAT**) for Special Medical Treatment or an order for treatment under a public health order, or an order of the NSW Supreme Court in exercise of its *parens patriae* jurisdiction.

Statutory requirements

Some procedures authorised by legislation may proceed without consent, for example, compulsory drug and alcohol testing of blood following a road accident.

Legislation may also impose specific processes that must be followed to lawfully provide treatment with or without consent. For example, there are specific methods to obtain consent and forms to record consent:

- for patients receiving electro-convulsive therapy and for surgical treatment provided to involuntary patients under the *Mental Health Act 2007*
- for involuntary treatment for severe substance dependence under the *Drug and Alcohol Treatment Act 2007*
- for treatment provided to inmates in a corrective facility under section 73 of the *Crimes (Administration of Sentences) Act 1999*
- for Special Medical Treatment under the *Guardianship Act 1987*.

In cases where treatment is authorised without consent, it is good clinical practice to engage with the patient and/or their Person Responsible in discussing, documenting and progressing the planned treatment.

Further guidance

- Section 9 – Consent for patients being treated under the *Mental Health Act*
- NSW Health Policy Directive *Blood and Alcohol Sampling by Hospital Staff* (PD2005_495)

4.3. What are the requirements for obtaining a valid consent?

Four core criteria must be met:

- the patient giving consent must have **capacity**
- the consent must be **freely given**
- the consent must be **sufficiently specific** to the procedure or treatment proposed
- the consent must be **informed**.

The four criteria for a valid consent must be met irrespective of whether the consent is in writing or oral. The mere mechanical signing of a consent form is, of itself, of limited value and is not necessarily a evidence of a valid consent.

4.3.1. Capacity

The patient must have the capacity to give consent. A person has decision making capacity if they can:

- understand the facts and choices involved
- weigh up the consequences and
- communicate their decision.

Legally, adults are presumed to have capacity to consent to or refuse medical treatment unless otherwise indicated. Capacity or lack of capacity should not be assumed on the basis of a patient's diagnosis or condition. For example, a patient with an intellectual disability may have capacity to make decisions about their own health treatment if information is provided to them in an appropriate manner or with appropriate assistance. See section 4.8.7 on making 'reasonable adjustments' to support inclusive and accessible services to people with a disability. Essentially, information should be provided in the format that is more

typically used by the client – for example, picture symbols, large print. Patients should be assisted or supported to make their own decisions as far as possible.

Section 33(2) of the *Guardianship Act 1987* provides that a person is incapable of giving consent to the carrying out of medical or dental treatment if the person:

(a) is incapable of understanding the general nature and effect of the proposed treatment, or
(b) is incapable of indicating whether or not he or she consents or does not consent to the treatment being carried out.

The NSW Department of Communities and Justice *Capacity Toolkit* also provides some useful, general principles to follow when assessing capacity:

- always presume a person has capacity
- capacity is decision-specific (for example capacity may fluctuate (see below) or certain simple health treatments may be within a person's capacity to consent whilst others may not)
- don't assume a person lacks capacity based on appearances
- assess the person's decision making ability not the decisions they make
- respect a person's privacy
- substitute decision making is a last resort.

A person's capacity may fluctuate from time to time throughout a treatment process as a result of an illness or condition that worsens sporadically such as a mental illness or delirium. The effects of drugs, alcohol or anaesthetics may also render a person temporarily unable to understand the consent process.

An involuntary patient under the *Mental Health Act 2007* does not necessarily lack capacity for making treatment decisions. Health Practitioners will need to consider whether the mental illness suffered by the person is affecting their capacity to consent to the medical treatment at that time.

Minors with sufficient maturity and intelligence to fully understand the procedure or treatment proposed have the capacity to consent (Mature Minors). If a Minor is assessed as *not* having the necessary level of maturity in relation to the treatment being discussed, the consent of a parent or guardian must be obtained.

Where there remains ambiguity or uncertainty about a person's capacity it is advisable to seek expert assessment and advice.

Further guidance

- NSW Department of Communities and Justice *Capacity Toolkit*
- Section 8 – Minors

4.3.2. Freely given

Consent must be freely given. The patient must not be pressured, coerced or intimidated into giving consent by Health Service staff, a Health Practitioner, a carer or a family member. If a Health Practitioner has concerns about whether a patient is being coerced into giving consent, the Health Practitioner should consider asking to speak to the patient alone without the presence of other family members to explore the patient's view.

4.3.3. Sufficiently specific

The consent must be specific and is valid only for the condition being treated and the specified treatment or procedure about which the patient has been informed and agreed to.

Courts have ordered Medical Practitioners to pay compensation to patients where they have undertaken additional procedures outside the original consent, even where the additional procedure appeared clinically appropriate. While this will not prevent treatment required in an emergency, it reinforces the importance of ensuring the patient gives specific consent.

Example

The patient's situation: A surgeon was performing an operation on the colon for colon cancer on a 35-year-old female patient. The patient had capacity and had consented to the procedure. However, during the operation, the surgeon was concerned that the patient's ovaries and fallopian tubes looked abnormal. The surgeon requested the advice of a gynaecologist who attended the operating theatre and advised on the patient's condition during the operation. The gynaecologist considered that the fallopian tubes and ovaries were abnormal, with multiple cysts, and there was endometriosis in the patient's pelvis.

Treatment without specific consent: The surgeon proceeded to remove the patient's ovaries and fallopian tubes during the colon procedure without the patient's specific consent. The surgeon thought that the patient's ovaries and fallopian tubes would need to be removed, and that it was more convenient for the patient to perform the procedure whilst she was already in theatre.

Was the surgeon justified? No. The consent the patient provided was only valid with respect to the colon operation. As the surgeon had also removed the fallopian tubes and ovaries without the patient's consent, he could potentially be guilty of trespass to the person and found negligent. A patient must provide specific consent for each medical procedure unless the circumstances fall within a legally authorised exception to the rule, such as an emergency.

4.3.4. Informed

The patient must be informed in broad terms of the nature and purpose of the healthcare in a way the patient can understand.

Health Practitioners have a duty to provide the patient with enough information to enable them to gain a genuine understanding of the nature and effects of the operation, procedure or treatment, the risks associated with it and any alternatives to the proposed treatment.

The information provided to the patient as part of the consent process should take into account the patient's Health Literacy to ensure that it is understandable. This obligation includes the use of different communication tools as necessary, including shared decision making.

Further guidance

- Section 4.8 – How do I properly inform a patient about a procedure and warn of material risks?
- NSW Health Clinical Excellence Commission *Health Literacy Framework*

4.4. Does the consent need to be in writing?

The general law on consent does not require consent or the provision of information, including warnings about risks, to be in writing. Consent to the treatment or procedure must still be sought notwithstanding it is not always required in writing. Patient consent can be express, either orally or in writing, or it can be implied from a person's conduct. For example, a patient may freely hold out their arm to receive an injection and this action could imply their consent.

However, a written consent, using the consent forms attached to this Consent Manual (Attachments A-F) (or an electronic equivalent as discussed in section 4.11.1) will assist Health Practitioners in providing appropriate and adequate information to patients in line with community expectations and legal requirements.

Written consent must be obtained for significant treatment and procedures as set out at section 4.5. Written consent should also be sought where a Person Responsible is consenting to treatment on behalf of a patient. There are some exceptions to this set out at section 7.5.

Written consent may also assist if there are subsequent legal proceedings questioning the validity of consent. In such cases, written consent will provide strong contemporaneous evidence of what was discussed and the patient's consent and views. While a written consent is not a legal document, it can be used in legal proceedings as evidence. The absence of a written record of consent could give rise to the inference that the procedure has not been discussed or that consent has not been obtained.

Regardless of how consent is obtained it is important to make a note in the patient's Health Record. If there is a particular reason why consent was not obtained in writing, this should also be documented, as should any involvement of an accredited interpreter.

Further guidance

- Section 4.8.4 – Patient information forms, brochures or other prepared material about a treatment to inform a patient when obtaining consent
- NSW Health Policy Directive *Clinical Procedure Safety* (PD2017_032)
- NSW Civil and Administrative Tribunal, Guardianship Division *Consent to Medical or Dental Treatment Factsheet*

4.5. Significant procedures or treatments requiring written consent

The NSW Health consent forms attached to this Consent Manual (or an electronic equivalent as discussed in Section 4.11.1) must be used for significant treatment or procedures. Whether a procedure is regarded as 'significant' will be a matter of clinical judgment depending on the circumstances. Health Practitioners should have regard to local policies and procedures for consent requirements. As a guide, significant procedures include:

- all operations (excluding minor procedures)
- all procedures requiring general, spinal, epidural, or regional anaesthesia or intravenous sedation
- any invasive procedure or treatment where there are known significant risks (including rare but important risks) or complications (for example, insertion of a chest drain or central lines and any procedure involving penetration of the peritoneum, thoracic cavity, pericardium, epidural space, spinal canal or cranial cavity)
- blood transfusions or the administration of blood products (see NSW Health Policy Directive *Blood Management* (PD2018_042))
- any treatment for which the approval of a Human Research Ethics Committee (HREC) is required. Note that a Person Responsible cannot consent to treatment pursuant to a clinical trial unless the trial has been approved by the Guardianship Division of the NCAT
- where a written consent form is required as a condition of a special approval process for the provision of certain medical treatment (for example, provision of medical treatment under the Commonwealth Government Therapeutic Goods Administration Special Access Scheme may require written consent on an approved consent form)
- significant treatment which might pose a risk to the health of the patient (for example, cardiac catheterisation, antineoplastic agents (for example chemotherapy), or radiation therapy.

Significant procedures are also referred to as Level 2 or 3 clinical procedures for the purposes of NSW Health Policy Directive *Clinical Procedure Safety* (PD2017_032).

Further guidance

- Commonwealth Department of Health, Therapeutic Goods Administration *Special Access Scheme*.

4.6. Minor procedures or treatments

Unless local policies or profession specific standards require written consent, signed consent forms are not required for minor procedures. Minor procedures include brief procedures performed under local anaesthesia, insertion of IV cannulae, urethral catheterisation, or suture of minor lacerations.

Although a signed consent form is not required for minor procedures, the criteria for obtaining a valid consent must still be met. That is, the patient must have capacity to consent, the consent must be freely given and be sufficiently specific to the treatment, and the patient must be informed about the procedure and any material risks.

It is important that a patient's consent to a minor procedure is recorded in the patient's Health Record if a signed consent form is not used.

4.7. Patient consent forms and Health Records

Where a consent form, or other form referred to in this Consent Manual, is used, it should remain as a separate stand-alone form in the patient's Health Record. This does not prevent consent forms from being printed on the reverse side of admission forms, or from being published as part of an admission booklet.

It is essential that the patient information and consent processes be given adequate emphasis when admission decisions are made. Where the consent form is published as part of an admission booklet, the relevant sections of the form must not be separated. A copy of the consent form may be provided to the patient.

A consent form or record of consent is an essential element of care. The form and entries in the patient's Health Record should be clear and legible. The use of abbreviations and symbols on consent forms is only permitted when these are clearly understood by the patient (for example, CPR).

A consent form can be uploaded into an electronic medical records system by scanning the form into an appropriate human readable and reproducible format and loading into a medical record system so that it can be readily located, viewed and printed as part of the electronic medical record. Typical formats include jpeg, tiff and pdf.

The elements of a valid consent must still be met when using an electronic consent form.

Further guidance

- Section 4.11.1 – Capturing consent electronically
- NSW Health Policy Directive *Health Care Records – Documentation and Management* (PD2012_069)

4.8. How do I properly inform a patient about a procedure and warn of material risks?

In order to be valid, consent must be informed. This requires the Health Practitioner to provide the patient with enough information to enable them to gain a genuine understanding of the:

- nature of the condition being treated
- proposed procedure or treatment and expected outcomes
- material risks and benefits of the proposed treatment, including alternative choices and whether the evidence supports one option over another.

Failing to warn a patient about the material risks of a proposed procedure could be a breach of the Health Practitioner's duty of care to the patient and could give rise to legal action for negligence.

A risk is material if, in the circumstances, a reasonable person in the patient's position, if warned of the risk would be likely to attach significance to it. A risk is also material if the Health Practitioner is, or should reasonably be aware, that a particular patient, if warned of the risk, would be likely to attach significance to it. It is important for Health Practitioners to explore what specific information is likely to be significant to each patient.

Information should be provided to the patient in a way which recognises the patient's Health Literacy level. A patient's Health Literacy can be improved by simplifying information, checking in to ensure understanding and supporting people to self-manage their health or use supported decision making where appropriate.

Careful consideration must also be given to using trauma-informed care principles and ensuring that the information provided enables a genuine, empowered choice.

Example

The patient's situation: A 33-year-old man is having back surgery to alleviate pain in his lower spine as a result of a protruding disc. The man works as a hairdresser and is a single father of three young children. He has told his surgeon that he can cope with the pain although he hopes that the operation might reduce the pain and possibly allow him to engage in more exercise. He has emphasised that he cannot take more than 8 weeks leave from his job as he is the sole income provider for his family.

The risk: The operation carries a 1 in 1000 risk of spinal nerve damage leading to leg and muscle weakness which can take up to 12 months to repair with rehabilitation.

What should the patient be told? The surgeon has a duty to inform the patient of the risk (among other risks including ongoing pain and non-resolution of symptoms) of damage to the spinal nerves even though it is considered to be extremely rare. The risk is material to the man's decision to undergo the surgery because of his career as a hairdresser and his role as sole parent of three young children.

The patient has conveyed information regarding his situation to the surgeon, which should be factored into the surgeon's consideration of what is material to this patient and this patient's circumstances. It is also relevant that the patient's current situation, although not ideal, is tolerable. Therefore, even an unlikely risk of severe nerve damage requiring 12 months of rehabilitation might deter him from proceeding with the surgery – making it material to this patient.

4.8.1. Treatment or procedures that are outside accepted practice/contrary to clinical guidelines

If a Health Practitioner is aware that the proposed treatment or procedure is:

- outside accepted practice
- likely to be different from treatment that would be offered by their peers in the same clinical setting
- contrary to relevant clinical guidelines; or
- an off-label use/contrary to the manufacturer's indication for use,

there is a particular onus to draw this to the patient's attention. The Health Practitioner must explain the clinical rationale for choosing that treatment or procedure as part of the consent process. This, and any discussion relevant to the patient's decision to proceed, should be documented in the Health Record.

4.8.2. Treatment or procedures that involve new technologies or techniques, or technologies or techniques new to the Health Practitioner(s)

Where a Health Practitioner is proposing a new or novel procedure, such as a procedure using a new technology or device, the Health Practitioner must inform the patient that the procedure or treatment is new to their practice and provide the patient with details of their previous (potentially limited) experience with the procedure or treatment as part of the consent process. This discussion should be documented in the Health Record. The discussions should include:

- the risks and benefits of the new technologies or techniques
- that there may be unforeseeable or unknown risks or outcomes due to the experimental, un-validated nature of the procedure
- evidence or lack of evidence regarding the treatment or technique.

Health Services should have processes in place to ensure that a patient who decides not to consent to a new procedure can be offered alternative treatment.

Further guidance

- NSW Health Guideline *NSW Framework for New Health Technologies and Specialised Services* (GL2018_023)

4.8.3. Guidelines for informing patients about the risks associated with medical treatment

As a guide, Health Practitioner's advising patients about proposed treatment should consider discussing:[1]

- the possible or likely nature of the illness
- the proposed approach to investigation and treatment including
  - what the proposed approach entails
  - the expected benefits
  - common side effects and material risks
  - whether the procedure is conventional or experimental and, if novel or experimental, that some of the risks may be unknown
  - who will undertake the intervention
- alternative options for diagnosis and treatment
- the benefits and risks of different options, including options to defer the decision
- the degree of uncertainty of the diagnosis and any therapeutic outcome
- the likely outcome of not having the diagnostic procedure or treatment, or of not having any procedure or treatment at all
- the likelihood of complete resolution of the clinical problem and symptoms, or chance of improvement and chance of recurrence
- level of evidence for proposed intervention
- location of procedure and length of stay
- expected timeframe for recovery
- option of seeking a second opinion
- any significant long-term physical, emotional, mental, social, sexual, or other outcome which may be associated with the proposed intervention
- where the treatment involves an 'implantable device' (such as vaginal mesh, breast implants) the manufacturer's provided consumer information
- the time and cost involved, including any out-of-pocket expenses.

Clinical judgment about how to convey risks will be influenced by several factors. These include:

- the seriousness of the patient's condition
- the nature of the intervention (complex interventions require more information)
- the likelihood of harm and the degree of possible harm
- the questions asked by the patient
- the patient's Health Literacy level and the patient's cognitive capacity
- accepted medical practice

The Health Practitioner should:

- communicate information and clinical opinions in a form the patient should be able to understand, using plain language, without any medical or technical jargon.
- allow the patient enough time to decide. The patient should be encouraged to reflect on opinions, ask more questions, and consult with their family, a friend or an advisor. The patient should be assisted in seeking another medical opinion where this is requested
- repeat key information to help the patient understand and remember it
- give written information or use diagrams/pictures/photos, where appropriate, in addition to talking to the patient
- pay careful attention to the patient's responses to help identify what has or has not been understood
- use a competent, registered interpreter when the patient is not fluent in English or use AUSLAN sign interpreter if required.

1 The National Health and Medical Research Council (NHMRC) Guidelines, *General Guidelines for Medical Practitioners on Providing Information to Patients 1993, revised 2004, (now rescinded, however the advice remains relevant and appropriate.)*

4.8.4. Patient information forms, brochures or other prepared material about a treatment to inform a patient when obtaining consent

Prepared material about a procedure or treatment can be useful as a means of stimulating discussion and for guiding the Health Practitioner when informing the patient.

Prepared material should:

- be up to date, accurate and appropriate for the patient
- be in plain language (Easy English) that is easy to understand or translate
- contain all inherent risks of the procedure. If a risk is more likely and/or has significant consequences, additional detail should be included
- ideally be provided before meeting with the patient to give the patient time to consider the information and prepare questions for the Health Practitioner
- be available in a variety of languages and formats (for example, large print).

Providing prepared material, without discussion, will not be enough to discharge the Health Practitioner's duty to fully inform the patient about the proposed treatment. The Health Practitioner should assist the patient to understand the material and provide further explanation if required. Health Practitioners should also check that information is up to date and accurate. An inadequate, inaccurate or out-dated information sheet may undermine the assertion that a patient has been properly informed.

If a patient is provided with a copy of prepared material as part of obtaining consent, this should be recorded in the Health Record and, ideally, a copy of the prepared material attached to the consent form.

4.8.5. Aboriginal Patients

NSW Health Policy Directive *Aboriginal and Torres Strait Islander Origin – recording of Information of Patients and Clients* (PD2012_042) outlines the requirements for collecting and recording accurate information on whether clients of NSW Health services are Aboriginal and/or Torres Strait Islander. If the patient identifies as Aboriginal and/or Torres Strait Islander, they should be offered the services of an Aboriginal Hospital Liaison Officer or Aboriginal Health Worker where available.

Acknowledgement and understanding of cultural sensitivities may assist in discussions around consent to recommended medical treatment. The National Safety and Quality Health Standards (NSQHS) states that Aboriginal and Torres Strait Islander patients may have the capacity to make decisions but also choose to involve a substitute decision maker in the planning and care processes. Communication strategies need to be clear and interactive to enable culturally appropriate ways of working and sharing understandings to enable good clinical decision making. Communication should be respectful of culture, adhere to cultural protocols and respect Aboriginal and Torres Strait Islander knowledge.

In obtaining consent, clinicians should be aware of potential past and existing trauma experienced by Aboriginal patients. Ensuring trauma-informed practice means discussing consequences that are clearly connected to the behaviour, delivered with genuine empathy and respect. Trauma-informed practice uses words that encourage thinking, and preserve connections between people.

In addition, consideration should be given to the level of Health Literacy of Aboriginal patients. A range of factors are linked to each person, their environment and upbringing that can either support or interfere with the development of individual Health Literacy. In some cases, the likelihood of lower individual Health Literacy might be increased where disadvantage and vulnerabilities connect. Individual Health Literacy is also dynamic: it can fluctuate depending on issues such as illness, stress and where the person is in their life course.

Example

Sheree is a 30 year old Aboriginal mother with 3 young children at home in the care of her husband. A neighbour has brought her to a busy emergency department at 7:15am with a cut to her hand sustained while preparing breakfast. Sheree is briefly seen by the triage nurse, who assesses the wound as stable and not actively bleeding. However, Sheree is likely to need stitches. She is prioritised as acute but told there would be some waiting time because of more urgent cases.

Sheree is anxious and distressed. Her neighbour is concerned for her welfare and is also aware that Sheree's husband has an important meeting at work that morning. Frustrated with waiting, Sheree's neighbour asks hospital staff about alternative care available. The Aboriginal Hospital Liaison Officer (AHLO) is contacted who advises that care could be provided at the local Aboriginal Medical Service (AMS). The AHLO is able to assist Sheree in making a priority appointment. Sheree and her neighbour decide to leave with the intention of visiting the AMS as soon as the children are organised and leave for school.

The primary duty owed by the hospital in this scenario is to assign an appropriate priority through the triage process and to observe Sheree in the waiting area for any deterioration in her condition. The hospital's duty of care also extends to providing Sheree with clearly communicated and appropriate advice, and involving other hospital staff such as the AHLO where appropriate.

Further guidance

- The National Safety and Quality Health Service Standards, User Guide for Aboriginal and Torres Strait Islander Health, 2017
- NSW Health Policy Directive – Aboriginal and Torres Strait Islander Origin – Recording of Information of Patients and Clients (PD2012_042)
- NSW Health Policy Directive – Emergency Department Patients Awaiting Care (PD2018_010)

4.8.6. Patients from culturally and linguistically diverse (CALD) backgrounds

Facilitating conversations and treatment decisions with patients from a range of diverse cultural and linguistic backgrounds can be challenging in a health care setting, where complex concepts, procedures, risks and alternative outcomes must be communicated. Health Practitioners should consider the patient's culture and trauma experience and how that might impact the consent process. Asking a patient what matters most to them may assist in understanding their health care needs.

NSW Health policy requires the use of accredited interpreters (in person or by telephone) when obtaining consent from patients who are not fluent in English or whose preferred language is a language other than English for significant treatment or any procedure where written consent is required. Any consent obtained without the presence of an accredited interpreter where an interpreter is required may be invalid. Consent for treatment of patients who are not fluent in English, or whose preferred language is not English, may not be valid if it is obtained through a child, family member, other patient, visitor or non-accredited staff member acting as an interpreter.

Bilingual Health Practitioners who are highly proficient in a language other than English may consult and communicate directly with their patients in the ordinary course of patient care. This is to be distinguished from interpreting. In these cases, the Health Practitioner must make a professional assessment that they can fully discharge their professional duty with regard to obtaining the patient's consent to the procedure or treatment in the patient's preferred language, for example, where a Health Practitioner is fluent in the patient's language. An appropriate notation should be made in the patient's Health Record and on the consent form that consent was sought by the practitioner in the patient's native tongue. The Health Practitioner in this situation would not be the interpreter for the purposes of the consent form.

Where a Medical Practitioner seeks consent in their private rooms for a procedure to be performed in a public hospital, the same requirements to use an accredited interpreter apply.

Example

A 45-year-old woman, Latika, arrives at the hospital for a hysterectomy. She speaks only basic English. A signed consent form is on Latika's Health Record along with an information sheet for her operation, which is written in English. On inspection, there is no record of an interpreter having been present at the consultation and no indication that any information has been provided in Latika's first language.

On the information available, the signed consent form in the file would not be valid. Latika should be re-consented by the admitting surgeon before the surgery with an interpreter present. This process should ensure a complete discussion of risks, benefits and possible side effects as well as alternatives to the treatment. If the surgeon is bilingual and decides they can communicate directly with the patient in her language to obtain consent, this should be documented.

As surgery is a significant treatment or procedure, the consent must be in writing and should be signed by the surgeon as well as the interpreter and the patient and filed on the patient's Health Record. A copy can be provided to Latika if requested.

Further guidance

- NSW Health Policy Directive *Standard Procedures for Working with Health Care Interpreters* (PD2017_044)

4.8.7. Other communication difficulties (sensory and communication disability)

Some patients may have a sensory disability (for example, they may be deaf, hearing impaired, blind and/or vision impaired) or have a communication disability (for example, impairment of language or complex communication needs). In these cases, the Health Practitioner should rely on appropriate communication aids according to the circumstances. For example, information about Auslan sign language interpreters is available from the Health Care Interpreter Service.

The law requires Health Services to make 'reasonable adjustments' to support inclusive and accessible services to people with a disability. Failure to make reasonable adjustments may be discrimination. In a health care setting in the context of obtaining consent, some examples of reasonable adjustment could include:

- adjusting communication methods by considering the patient's communication needs. This could include using tablets, low vision aids, speech generating devices or a cues book
- including and supporting the patient's carer, family member, guardian or disability support staff as expert care partners
- additional consultation to allow ample time for understanding and reading provided information
- providing patient information in alternate formats such as easy read documents.

The NSW Council for Intellectual Disability *Consent to Medical Treatment Fact Sheet* gives the following advice to assist Health Practitioners when seeking consent from a patient with an intellectual disability in ensuring the person understands and can make their own decision:

- involve someone who the person likes talking to
- talk about the treatment somewhere that is quiet and where the person feels relaxed
- try to use words the person knows. If you have to use difficult words, try to explain them simply
- if the person has an alternative communication system, use that
- use pictures or diagrams that show the problem and the proposed treatment
- stick to the basic information. Do not overload the person with detail; and
- give the person time to think about the information, ask questions, and then have another talk.

Further guidance

- AUSLAN
- NSW Health Policy Directive *Responding to Needs of People with Disability during Hospitalisation* (PD2017_001)
- NSW Health Policy Directive *Provision of Services to People with an Intellectual Disability and Mental Illness – MoU and Guidelines* (PD2011_001)
- The NSW Council for Intellectual Disability *Consent to Medical Treatment Fact Sheet.*
- Department of Communities and Justice *A NSW Government agency guide for effective communication for people with a sensory disability.*

4.9. Can information be withheld from the patient?

There are two (2) situations where a Medical Practitioner may be justified in withholding information from a patient.

1. *Where a patient does not want the information* and expressly directs the treating Medical Practitioner to make decisions on their behalf. Even in this case, the Medical Practitioner should give the patient basic information about the diagnosis and treatment. Any direction or views expressed by the patient must be documented in the patient's Health Record.
2. *Therapeutic privilege*. Information could be withheld in rare circumstances where the Medical Practitioner holds a reasonable belief that providing information would be damaging to the patient's health. This will only arise in very limited circumstances and requires the Medical Practitioner to make a judgment, based on reasonable grounds, that the patient's physical or mental health might be seriously harmed by the information. The types of factors governing therapeutic privilege include the patient's personality, temperament or attitude; their level of understanding; the nature of the treatment and the likelihood of adverse effects resulting from the treatment. In these circumstances, the Medical Practitioner should clearly record the reasons for exercising therapeutic privilege in the patient's Health Record. Health Practitioners should consider seeking assistance in communicating with patients and families about difficult matters and consult with colleagues before making a decision on withholding information.

Information cannot be withheld from a guardian or Person Responsible making decisions on behalf of a patient under the *Guardianship Act 1987.* Where it is considered that the Person Responsible is not capable of performing their functions the Medical Practitioner should certify this in writing and the next person in the Person Responsible hierarchy should be consulted.

Further advice should be sought from Ministry of Health Legal Branch or the local Director of Medical Services if there is any uncertainty about whether information can be withheld from a patient.

4.10. Does written consent need to be obtained for every procedure or step in a treatment program?

Some treatments involve several separate procedures or the administration of medication or blood products over a period of time or a series of patient visits. Antineoplastic agents (for example, chemotherapy) and the administration of blood products to patients with haemophilia are examples of a treatment program. Wound therapy dressing changes could also be considered a treatment program.

Consent to undergo the treatment program should be obtained and documented before beginning the course of treatment. An explanation of the treatment program, including the proposed duration of the program, the steps or separate treatments/procedures involved, and the material risks associated with the treatment program should be provided. A further consent form for each stage of the treatment program will generally not be necessary.

A new consent form should be completed if a *new* treatment is proposed which was not previously explained to the patient, where alternative treatments become available, or if new risks associated with the treatment are identified.

Health Practitioners should also remain alert to any issues or concerns raised by the patient during the treatment program. Before continuing with the treatment program, such concerns should be discussed with the patient and documented in the patient's Health Record. If the issues raised are significant, or result in a material change to the treatment program, a new form should be completed to capture the discussions.

An unexpected change to a patient's treatment cannot be part of a 'treatment program'. For example, if a patient consents to surgery, and after that surgery has been performed, requires to be returned to theatre as a result of a complication such as a post-surgical bleed, a new consent should be obtained, unless the situation is an emergency and consent is therefore not required, or cannot be obtained in the circumstances.

4.11. Can consent be captured electronically, and can a consent form be faxed or emailed?

4.11.1. Capturing consent electronically

Some electronic medical records programs have capability to capture the patient's consent to a proposed treatment or procedure. It is important to remember that the elements or four criteria of a valid consent must be met regardless of the method used to capture consent.

Further, whilst there are no legal barriers to capturing consent electronically, processes must be in place to maintain the integrity of the electronic record. For example, electronic records should be protected from being corrupted from any changes to software.

There are some other important issues to consider:

- Information provided to a patient as part of obtaining consent must be documented. This can be achieved a number of ways, depending on the electronic medical records program in use – through free text typing by the Health Practitioner, uploading a voice recording of the Health Practitioner advising the patient about the procedures and material risks, or using a pamphlet as part of the information provision and then uploading it or uploading a photo of the pamphlet in the electronic medical record.
- If the facilities are available to the Health Service, the patient may be provided with an electronic device and use a compatible instrument to manually sign the device to signify consent. Also, a patient's voice recording giving consent may be uploaded to the Health Record. These recordings must be clearly linked to the treatment the patient is consenting to and must be readily accessible in the patient's Health Record.
- There must be processes in place to verify the identity of the patient or the patient's Person Responsible either through a photo identification or Patient Identifier (including patient identification bands) before consent being recorded. The Health Service must ensure that the electronically recorded consent is as reliable as the hard copy version in terms of security, storage and access. If exceptional circumstances arise whereby the Person Responsible is providing consent over the telephone, there must be a local level policy in place to confirm the identity of the Person Responsible and their connection to the patient. This could include asking standard questions to confirm the Person Responsible's personal information. The details of identity confirmation must be documented in the patient's Health Record.
- The user interface elements must indicate that the Health Practitioner had a discussion around the proposed treatment, material risks and consequences. The act of checking or ticking the user interface element(s) to indicate what was discussed and that valid consent was obtained must record the user that performed that action in a permanent log, together with time and date stamps.
- A physically signed, hard copy consent form may be uploaded in an appropriate human readable format to form part of the patient's electronic medical record. Examples of electronic formats include jpeg and pdf.
- If subsequent changes to the state or content of any user interface elements or scanned documents are allowed, the user interface must indicate clearly that changes have been made without any action required by the viewer and must log all changes with clear identification of the user making the change and the date and time of each change. Where changes are made to a scanned document and a new version is created, the original scanned copy must be retained for medico-legal reasons.

4.11.2. Faxed, emailed, photocopied consent forms and the use of electronic signatures

An original consent form should be obtained where possible as it is preferable to a faxed, photocopied or scanned and emailed form. If it is not possible to obtain an original consent form, a faxed, photocopied or scanned version can be retained, provided it is of reasonable quality and it is possible to verify the signature of the patient/Person Responsible. When faxing, copying or scanning consent forms, care should be taken to ensure that double-sided documents are captured in their entirety.

The use of a stamp signature or electronic equivalent signature as part of the consent process should be discouraged as they make it difficult to verify whether the Health Practitioner signed the documentation or whether it was stamped by someone else. The use of these methods could be used later to call into question whether the Health Practitioner actually turned their mind to making that decision.

Further guidance

- NSW Health Policy Directive *Health Care Records – Documentation and Management* (PD2012_069)

4.12. How long does consent remain valid?

The general rule is that consent will remain valid until it is withdrawn by the patient or until the patient's circumstances change in a material respect.

Some examples of situations which could mean that the patient's circumstances have changed materially and require a new consent (either using a new form or simply recording the consent in the Health Record) are as follows:

- where a patient who was incapable of providing their own consent becomes well enough and capable to provide consent to future care and treatment
- the development of alternative treatments to the recommended procedure
- the identification of new risks or side effects associated with the recommended procedure
- where consent was provided 12 months ago for a major procedure but there may be unrecognised cognitive changes in the patient.

Consent should also be revisited if a significant period of time has lapsed since the original consent was obtained. What constitutes a significant amount of time will depend on the individual circumstances of the case including the procedure for which consent is sought.

Example

A patient signs a consent form to undergo an elective septoplasty (surgery to correct a deviated septum). He is classified as urgency category 3 – surgery recommended within 365 days. When the patient is admitted to hospital for the surgery, 14 months have passed since the date that the consent form was signed. However, as the patient's health has not changed in that time, and there have been no changes in the way that the surgery will be performed, the consent form is still valid. Even so, the patient's consent should still be re-confirmed verbally by the operating surgeon immediately prior to the surgery.

Consents granted by the Guardianship Division of the NCAT or the Public Guardian will not usually have an unlimited timeframe. Consents will usually be valid for 3, 6 or 12 months depending on the nature of the proposed treatment. Patients subject to such consents should be reviewed before the expiry of the consent orders and, where necessary, a further application or request for consent should be made where treatment is to be continued or modified.